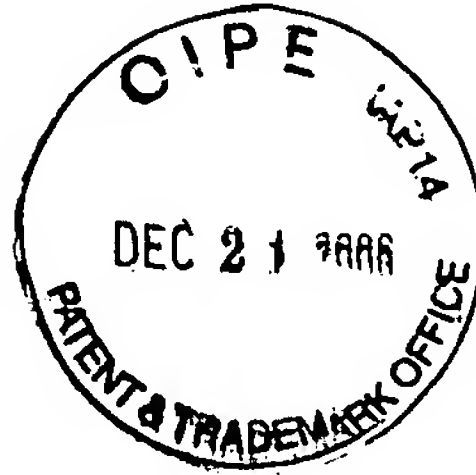


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**IN THE UNITED STATES PATENT  
AND TRADEMARK OFFICE**



Appl. No. : 10/562,742  
Applicant : Kyoichi SHIMOMURA et al  
Filed : December 29, 2005  
Art Unit : 1614  
Confirm. No.: 7803  
Docket No. : 05832/HG  
Customer No.: 01933

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Date of Deposit: December 21, 2006

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*Lori Valdes*

Lori Valdes

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**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450


S I R :

A copy of each of the publications identified in the enclosed Forms PTO/SB/08A and PTO/SB/08B is enclosed herewith (except for the United States patents). Cite Nos. 1-7 and 9 are identified in the enclosed copy of the English language International Search Report in PCT/JP2004/009766. Cite Nos. 8 and 10-12 are identified and discussed in the present specification, pages 1-3.

It is requested that said publications be considered and that a copy of the enclosed Form PTO/SB/08A with the Examiner's

initials in the left column be returned to the undersigned attorney.

Respectfully submitted,



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HG/lpv

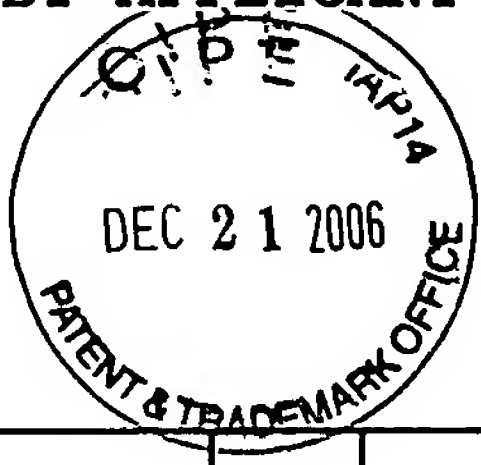
Encs.: Forms PTO/SB/08A and PTO/SB/08B and publications  
identified thereon; International Search Report

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PTO/SB/08A (08-00)

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

|  |   |                      |                         |                        |          |
|--|---|----------------------|-------------------------|------------------------|----------|
| Substitute for Form 1449A/PTO<br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br> |   | Application Number   | 10/562,742              |                        |          |
|  |   | Filing Date          | December 29, 2005       |                        |          |
|  |   | First Named Inventor | Kyoichi SHIMOMURA et al |                        |          |
|  |   | Group Art Unit       | 1614                    |                        |          |
|  |   | Examiner Name        |                         |                        |          |
| Sheet  | 1 | of                   | 2                       | Attorney Docket Number | 05832/HG |

## U.S. PATENT DOCUMENTS

| Exam.<br>Inits* | Cite<br>No <sup>1</sup> | Document Number | Kind<br>Code <sup>2</sup> | Name of Patentee or<br>Applicant | Publication<br>Date MM-DD-YYYY | Relevant<br>Portion |
|-----------------|-------------------------|-----------------|---------------------------|----------------------------------|--------------------------------|---------------------|
|                 | 1                       | 5,776,972       |                           | BARBER et al                     | 07-07-1998                     |                     |
|                 | 2                       | 4,547,513       |                           | IWAO et al                       | 10-15-1985                     |                     |

## FOREIGN PATENT DOCUMENTS

| Exam<br>Inits* | Cite<br>No <sup>1</sup> | offc <sup>3</sup> | Document Number <sup>4</sup>       | Kind<br>Code <sup>5</sup> | Name of Patentee or<br>Applicant | Publication<br>Date MM-DD-YYYY | Relevant<br>Portion | T <sup>6</sup> |
|----------------|-------------------------|-------------------|------------------------------------|---------------------------|----------------------------------|--------------------------------|---------------------|----------------|
|                | 3                       | JP                | 2002-524444                        | A                         | ADOLOR CORP.                     | 08-06-2002                     |                     | *              |
|                | 4                       | JP                | 9-020659                           | A                         | MERCK PATENT GmbH                | 01-21-1997                     |                     | *              |
|                | 5                       | JP                | 62-221680                          | A                         | SANTEN PHARMA.                   | 09-29-1987                     |                     | *              |
|                | 6                       | JP                | 60-139679                          | A                         | SANTEN PHARMA.                   | 07-24-1985                     |                     | *              |
|                | 7                       | JP                | 2004-002352                        | A                         | SANTEN PHARMA.                   | 01-08-2004                     |                     | *              |
|                |                         |                   | *English language<br>Abstract only |                           |                                  |                                |                     |                |

Examiner  
SignatureDate  
Considered

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Place a check here if English translation is attached.

DATE MAILED: December 21, 2006

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|   |                       |   |   |                        |                         |
|---|-----------------------|---|---|------------------------|-------------------------|
| Substitute for Form 1449A/PTO<br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b> |                       |   |   | Application Number     | 10/562,742              |
|   |                       |   |   | Filing Date            | December 29, 2005       |
|   |                       |   |   | First Named Inventor   | Kyoichi SHIMOMURA et al |
|   |                       |   |   | Group Art Unit         | 1614                    |
|   |                       |   |   | Examiner Name          |                         |
| Sheet   | 2                     | of  | 2 | Attorney Docket Number | 05832/HG                |
| OTHER DOCUMENTS - NON-PATENT LITERATURE DOCUMENTS   |                       |   |   |                        |                         |
| Examiner Initials <sup>1</sup>  | Cite No. <sup>1</sup> | Include name of author (in CAPITAL LETTERS), title of article, title of item, date, page(s), volume-issue number(s), publisher, city and/or country where published                   |   |                        | T <sup>2</sup>          |
|   | 8                     | H. OHARA et al, "Mechanism of Hyperalgesia in SART Stressed (Repeated Cold Stress Mice: Antinociceptive Effect of Neurotropin", <u>JAPAN, J. PHARMACOL.</u> , 57, pp. 243-250 (1991). |   |                        |                         |
|   | 9                     | H. VANEGAS et al, "Effects of antagonists to high-threshold calcium channels upon spinal mechanisms of pain, hyperalgesia and allodynia", <u>PAIN</u> , 85, pp. 9-18 (2000).          |   |                        |                         |
|   | 10                    | K.K. MIKUSU, <u>OPIOID NO SUBETE</u> , pp. 25-36 (1999).  |   |                        | *                       |
|   | 11                    | K.K. MIKUSU, <u>OPIOID NO SUBETE</u> , pp. 213-232 (1999).  |   |                        | *                       |
|   | 12                    | K.K. MIKUSU, <u>OPIOID CHIRYO</u> , PP. 246-253 (2000).   |   |                        | *                       |
|   |                       | *English language abridged translation only   |   |                        |                         |
| Examiner Signature  |                       |   |   | Date Considered        |                         |

\* EXAMINER: Initial if document considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Place a check here if English translation is attached.

DATE MAILED: December 21, 2006

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/JP2004/009766

## A. CLASSIFICATION OF SUBJECT MATTER

Int.Cl<sup>7</sup> A61K45/00, 31/428, A61P25/00, C07D207/09, 277/66

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Int.Cl<sup>7</sup> A61K45/00, 31/428, A61P25/00, C07D207/09, 277/66

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

REGISTRY/MEDLINE/CAPLUS/EMBASE/BIOSIS (STN)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages   | Relevant to claim No. |
|-----------|--|-----------------------|
| X<br>Y    | JP 2002-524444 A (Adolor Corp.),<br>06 August, 2002 (06.08.02),<br>Claims 4, 5<br>& WO 00/14065 A  | 1, 2, 7, 9<br>5, 6    |
| X<br>Y    | JP 9-020659 A (Merck Patent GmbH.),<br>21 January, 1997 (21.01.97),<br>Claims 5, 8<br>& EP 0752246 A2 & US 5776972 A1  | 1, 2, 7, 9<br>5, 6    |
| Y         | Vanegas H. et al., 'Effects of antagonists to<br>high-threshold calcium channels upon spinal<br>mechanisms of pain, hyperalgesia and allodynia.',<br>Pain. 2000 March; 85(1-2):9-18. | 3, 4                  |

☒ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

\* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search  
06 September, 2004 (06.09.04)

Date of mailing of the international search report  
28 September, 2004 (28.09.04)

Name and mailing address of the ISA/  
Japanese Patent Office

Authorized officer

Facsimile No.

Telephone No.

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/JP2004/009766

## C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages   | Relevant to claim No. |
|-----------|--|-----------------------|
| Y         | JP 62-221680 A (Santen Pharmaceutical Co., Ltd.),<br>29 September, 1987 (29.09.87),<br>Claim 1; page 1, right column, lines 16 to 18<br>(Family: none) | 3, 4                  |
| Y         | JP 60-139679 A (Santen Pharmaceutical Co., Ltd.),<br>15 October, 1985 (15.10.85),<br>Claim 1<br>& US 4547513 A   | 3, 4                  |
| E, A      | JP 2004-2352 A (Santen Pharmaceutical Co., Ltd.),<br>08 January, 2004 (08.01.04),<br>Full text<br>(Family: none)                                       | 1-4, 7, 9             |